DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Orcolon
Docket No. 91E-0224

AUG -2 1991

#19

The Honorable Harry F. Manbeck, Jr.
Assistant Secretary of Commerce
and Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Manbeck:

This is in regard to the application for patent term extension for U.S. Patent No. Re. 32,969, filed by Seymour F. Trager and Victoria S. Chylinski, under 35 U.S.C. 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Orcolon, the medical device claimed by the patent.

The total length of the review period for Orcolon is 1,551 days. Of this time, 1,141 days occurred during the testing phase and 410 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation involving this device was begun: December 31, 1986.

   The applicant claims October 13, 1986, as the date the investigational device exemption (IDE) became effective. However, FDA records indicate that the IDE was conditionally approved on December 31, 1986.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: February 13, 1990.

   The applicant claims July 29, 1987, as the date the premarket approval application (PMA) (P870044) was submitted. However, FDA records indicate that PMA No. P870044 was declared not fileable three times by FDA before being withdrawn by the applicant on June 27, 1988. [See 21 CFR 60.22 (d).] A second PMA (P900010) was submitted by the applicant and was accepted by FDA on February 13, 1990.

3. The date the application was approved: March 29, 1991.

   FDA has verified the applicant's claim that PMA No. P900010 was approved by FDA on March 29, 1991.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

for Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Franklin D. Wolffe
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